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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 16

[Docket No. FDA–2013–N–0365]

Administrative Detention of Drugs Intended for Human or Animal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is implementing administrative detention authority with respect to drugs intended for human or animal use as authorized by amendments made to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA's administrative detention authority with respect to drugs allows FDA to better protect the integrity of the drug supply chain. Specifically, FDA is able to administratively detain drugs encountered during an inspection that an authorized FDA representative conducting an inspection has reason to believe are adulterated or misbranded. This authority is intended to protect the public by preventing distribution or subsequent use of drugs encountered during inspections that are believed to be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.

DATES: This rule is effective June 30, 2014.

FOR FURTHER INFORMATION CONTACT: Charlotte Hinkle, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–5300, *FDASIAImplementationORA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

FDA's administrative detention authority with respect to drugs intended for human or animal use allows FDA to better protect the integrity of the drug supply chain. Specifically, administrative detention is intended to protect the public by preventing distribution or subsequent use of drugs encountered during inspections that may be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. FDA already has the authority to administratively detain devices, tobacco, and foods that FDA has reason to believe are adulterated or misbranded.

FDA is issuing this final rule under section 304(g) of the FD&C Act (21 U.S.C. 334(g)), as amended by section 709 of FDASIA, and section 701 of the FD&C Act (21 U.S.C. 371). Section 304(g) of the FD&C Act also authorizes FDA to administratively detain devices and tobacco products.

Summary of the Major Provisions

This final rule implements a regulation for the administrative detention of drugs. FDA is amending parts 1 and 16 (21 CFR parts 1 and 16) to create an implementing rule for this authority. The changes set forth the procedures for detention of drugs believed to be adulterated or misbranded and amend the scope of FDA's part 16 regulatory hearing procedures to include the administrative detention of drugs.

Costs and Benefits

The primary public health benefits from adoption of the final rule would be the value of the illnesses or deaths prevented because the Agency administratively detained a drug it has reason to believe is adulterated or misbranded; this benefit occurs only if the drug would not have been prevented from entering the market using one of the Agency's other enforcement tools. The estimated primary costs to FDA include marking or labeling the detained product and costs associated with appeals of detention orders. The Agency estimates the net annual social costs to be between $0 and $602,602.

I. Background

In the **Federal Register** of July 15, 2013 (78 FR 42381), FDA proposed regulations to implement its new authority to administratively detain drugs that an authorized FDA representative conducting an inspection under section 704 of the FD&C Act (21 U.S.C. 374) has reason to believe are adulterated or misbranded. As discussed in the preamble to the proposed rule, on July 9, 2012, President Obama signed into law FDASIA (Public Law 112–144). Title VII of FDASIA provides FDA with important new authorities to help it better protect the integrity of the drug supply chain. One of those new authorities is section 709, which amends section 304(g) of the FD&C Act to provide FDA with administrative detention authority with respect to drugs. Section 304(g) of the FD&C Act, as amended by FDASIA, provides FDA the same authority to detain drugs that section 304(g) already provides FDA with respect to devices and tobacco products. Once these implementing regulations with respect to drugs take effect, the amendments to section 304(g) of the FD&C Act will allow FDA to administratively detain drugs that an authorized FDA representative conducting an inspection under section 704 of the FD&C Act has reason to believe are adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.

II. Overview of the Final Rule Including Changes to the Proposed Rule

A. Revisions to Part 1

FDA is amending title 21 of the Code of Federal Regulations, part 1 to create an implementing regulation for the administrative detention of drugs. The amendment to part 1 consists of one section, § 1.980, under a new subpart, which is titled ''Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use.'' Section 1.980 sets forth the procedures for the administrative detention of drugs encountered during an inspection that are believed to be adulterated or misbranded. The new regulation is closely modeled on the current regulation for the administrative detention of devices (21 CFR 800.55). There are minor differences from the device regulation, including updates to statutory references to refer to drugs instead of devices and changes to language to conform to current **Federal Register** requirements. Since FDA issued the proposed rule on administrative detention of drugs, FDA has issued other regulations in part 1, requiring reassignment of the section number within part 1. No other changes have been made to the substance of the proposed regulation. Other than renumbering the section, FDA is finalizing the implementing regulations as proposed.

B. Revisions to Part 16

The amendment to part 16 is a technical change. This change amends a statement in § 16.1 so that the scope of part 16 regulatory hearing procedures also will include administrative

detention authority with respect to drugs.

III. Comments on the Proposed Rule

FDA received six comments in the docket for the July 15, 2013, proposed rule on administrative detention of drugs, three of which were responsive. However, after considering these comments, the Agency is not making any changes to the regulatory language included in the proposed rule. Relevant portions of the responsive comments are summarized and responded to in this document. The Agency did not consider nonresponsive comments in developing this final rule. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment and response to help distinguish between different comments. Similar comments are grouped together under the same number. The number assigned to each comment is purely for organization purposes and does not signify the comment's value or importance or the order in which it was received. Comments addressing the proposed implementing regulation for the administrative detention of drugs and FDA's responses follow.

A. Standard for Administrative Detention Order

In the proposed rule, FDA proposed that an administrative detention of drugs may be ordered when an authorized FDA representative, during an inspection under section 704 of the FD&C Act, has reason to believe that a drug is adulterated or misbranded. Two comments suggested the Agency modify the proposed standard for issuing an administrative detention order.

(Comment 1) One commenter stated that the term ''adulteration'' is very broad and suggested that, to ensure that patients continue to have access to safe medications, the Agency should add an element of potential risk of public harm to the detention standard.

(Response 1) The Agency does not have the authority to change the administrative detention standard, which is specified by statute. Section 304(g) of the FD&C Act provides, in relevant part: ''If during an inspection conducted under section 704 of a facility or vehicle, a drug which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer may order the drug detained (in accordance with regulations prescribed by the Secretary).'' Furthermore, we note that the terms ''adulterated'' and ''misbranded'' are well characterized by both the adulteration and misbranding provisions of the FD&C Act, its implementing regulations, and a substantial body of case law. For example, sections 501 and 502 of the FD&C Act (21 U.S.C. 351 and 352) provide criteria for determining whether a drug will be considered to be adulterated or misbranded, respectively. Because these terms are already well characterized, we do not believe it necessary or appropriate to further define or modify the meaning of these terms for the purposes of this rule.

(Comment 2) One commenter suggested that the Agency should administratively detain shipments based on a pre-determined, justified level of suspicion, with an example that the Agency may wish to scrutinize more closely shipments that are not from a known shipper or known consignor.

(Response 2) The commenter's reference to ''shipper and ''consignor'' indicate that the commenter is confusing administrative detention of a drug during an inspection under section 304(g) of the FD&C Act with the process of reviewing imported products under section 801(a) of the FD&C Act (21 U.S.C. 381). Under § 1.94, when it appears to FDA that an imported article may be subject to refusal of admission under section 801(a) of the FD&C Act, FDA provides a notice of that fact to the owner or consignee and provides them with an opportunity to introduce testimony. This notice is commonly called a ''Notice of Detention and Hearing'' (see, e.g., *FDA Regulatory Procedures Manual,* chapter 9, pp. 9–29) (Ref. 1) and is not related to administrative detention under section 304(g) of the FD&C Act.

B. Notification of Detention Order

In the proposed rule, FDA proposed that the detention order be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the drugs are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the drugs are located. If the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are detained, a copy of the detention order must be provided to the owner or user of the drugs if the owner's or user's identity can be readily determined. If detention of drugs in a vehicle or other carrier is ordered, a copy of the detention order must be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined. An FDA representative issuing a detention order must label or mark the drugs with official FDA tags that include certain information.

(Comment 3) One commenter requested that FDA immediately notify the party responsible (e.g., manufacturer or wholesaler) for the detained drug to enable drug owners to inform customers that their orders may be delayed as well as opened and checked by FDA.

(Response 3) We believe that the notice requirements set forth in the proposed rule, which we are adopting, together with the requirement that FDA label or mark the drugs subject to the detention order, address the commenter's concerns regarding FDA notification of detention orders to the owner, operator, or agent in charge of the place where the drugs are located. Furthermore, if the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are located, FDA also will provide a copy of the detention order to the owner or user of the drugs, if their identity can be readily determined. FDA expects such notification to be as timely as possible. The procedures FDA puts into place to implement this rule will address the notice requirements and help ensure that our investigators are appropriately educated and trained on the procedural requirements.

C. Appeals of Detention Orders

In the proposed rule, FDA proposed that the person who would be entitled to claim the drugs, if seized, may appeal a detention order.

(Comment 4) Two commenters suggested the Agency clarify that it is not the intent of the Agency to limit the manufacturer's ability to appeal a detention order.

(Response 4) Who may appeal a detention order is determined by Federal statute. Section 304(g) of the FD&C Act specifies who may appeal a detention order: ''Any person who would be entitled to claim a device, drug, or tobacco product if it were seized under [304(a)] may appeal . . . a detention of such device, drug, or tobacco product. . .''.

(Comment 5) One commenter expressed concern that a drug product subject to a detention order would be withheld from patients without due process, potentially creating a drug shortage.

(Response 5) We believe that the detailed notice and appeals procedures set forth in the proposed rule, which

includes the opportunity for an informal hearing within 5 working days after the appeal is filed, satisfy the elements of due process. We appreciate the commenter's concern that an administrative detention could lead to a drug shortage and note that the Agency has an active drug shortages program. Preventing drug shortages has been, and continues to be, a top priority for FDA, and we take great efforts to address, prevent, and mitigate drug shortages. Yet in making regulatory and enforcement decisions, FDA not only is concerned with the potential for drug shortages, but also with the potential for harm to patients caused by an adulterated or misbranded drug entering into commerce.

D. Movement of Detained Drugs

In the proposed rule, FDA proposed that, except as provided, no person may move a detained drug within or from the place where they were ordered detained until FDA terminates the detention or the detention period expires, whichever occurs first.

(Comment 6) Two commenters noted that administrative detention regulations should provide sufficient flexibility for movement in order to preserve product integrity during the detention process.

(Response 6) FDA believes that § 1.980(h)(3)(i) provides the flexibility sufficient to preserve product quality and integrity during an administrative detention. Paragraph (h)(3) states that an authorized FDA representative ''may approve, in writing, the movement of detained drugs for any of the following purposes: (i) To prevent interference with an establishment's operation or harm to the drugs.''

E. Notification of Detention Termination

In the proposed rule, FDA proposed that, if FDA decides to terminate a detention or when the determination period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the drugs to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(Comment 7) One commenter suggested adding language that FDA will notify, by telephone or other means of rapid communication, the person who received the original detention order or that person's representative of the detention notification.

(Response 7) We understand the concern raised by the commenter but do not believe that the notification of detention requirements should be revised to require notification by telephone or other means of rapid communication. As a general matter, current Agency practice with regard to administrative detentions is to concurrently notify the person who received the original detention order, or that person's representative, of the detention termination when a detention termination notice is sent by mail. We will consider incorporating such notification processes into Agency procedures to implement administrative detentions for drugs.

F. Enforcement Concerns

(Comment 8) One commenter expressed concern regarding the potential for variability of enforcement among FDA's investigators, particularly regarding potential adulteration charges under section 501(j) of the FD&C Act.

(Response 8) The authorities granted to FDA in Title VII of FDASIA, including the authority to enforce the prohibition against delaying, denying, limiting, or refusing an inspection under section 707 of FDASIA, are a comprehensive package, intended to enhance FDA's oversight of the global drug supply chain. Implementation of these new authorities will include measures to help ensure that our investigators are appropriately educated and trained on the new legal authorities and implementing procedures.

G. Foreign Inspections

(Comment 9) One commenter suggested that FDA highlight the intent and manner in which the Agency intends to collaborate with foreign governments to apply administrative detention authority abroad.

(Response 9) We appreciate this comment; however, the focus of this rule is not on our enforcement implementation, but on the process by which administrative detention of drugs occurs. If, in the future, we determine that administrative detention authority with respect to drugs has a unique application, we will evaluate what guidance or other information we will need to issue to help ensure transparency.

H. Harmonization With European Union Legislation

(Comment 10) One commenter suggested that to support global harmonization, FDA harmonize the administrative detention of drugs to the highest possible degree with the European Union Falsified Medicines Directive (EU Directive 2011/62).

(Response 10) FDA appreciates the comment. We do harmonize with legislation of our foreign regulatory counterparts to the extent possible and practicable. In 2011, the European Union (EU) Council issued the Falsified Medicines Directive in an effort to strengthen the EU's ability to detect falsified medicines and prevent their entry into the legitimate supply chain by adding new requirements in four main areas: Safety features, supply chain and good distribution practices, active pharmaceutical ingredients, and Internet sales (Ref. 2). This EU legislation, however, does not address administrative detention of drugs.

IV. Legal Authority

FDA is issuing this final rule under sections 304(g) and 701 of the FD&C Act and section 709 of FDASIA. Section 709 of FDASIA provides FDA authority to issue regulations regarding administrative detention authority with respect to drugs. Section 304(g) of the FD&C Act includes FDA's administrative detention authority with respect to drugs. The final rule is necessary for efficient enforcement of the FD&C Act.

V. Analysis of Impacts (Summary of the Regulatory Impact Analysis)

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule would not be an economically significant regulatory action as defined by Executive Order 12866.

If a rule has a significant economic impact on a substantial number of small businesses, the Regulatory Flexibility Act requires Agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. FDA has determined that this final rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may

result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The primary public health benefits from adoption of the final rule would be the value of the illnesses or deaths prevented because the Agency administratively detained a drug it has reason to believe is adulterated or misbranded; this benefit occurs only if the drug would not have been prevented from entering the market using one of the Agency's other enforcement tools. There may also be benefits from deterrence if administrative detention increases the likelihood that misbranded or adulterated products will not be marketed in the future.

The estimated primary costs to FDA include marking or labeling the detained product and costs associated with appeals of detention orders. However, other costs, such as loss in market value of a detained drug, may be incurred if FDA revokes the detention order on appeal. Given the history of administrative detention use with medical devices and foods, the likelihood is low of FDA issuing a detention order that is later revoked on appeal.

We estimate the annual costs using a range of 0 to 20 administrative detentions performed each year. The Agency estimates the net annual social costs to be between $0 and $602,602. The present discounted value over 20 years would be in the range of $0 to $8,965,196 at a 3 percent discount rate and in the range of $0 to $6,383,974 at a 7 percent discount rate.

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule would not have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

The full discussion of economic impacts is available in docket FDA–2013–N–0365 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 3).

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)). Therefore, clearance by the Office of Management and Budget is not required under the Paperwork Reduction Act of 1995.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. *FDA Regulatory Procedures Manual,* chapter 9, pp. 9–29.

2. ''Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2011/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products,'' *Official Journal of the European Union,* January 7, 2011, available at *http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf.*

3. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Administrative Detention of Drugs Intended for Human or Animal Use, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 16 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

Subparts L–P—[Added and Reserved]

■ 2. Add and reserve subparts L through P.

■ 3. Add subpart Q, consisting of § 1.980, to read as follows:

Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use

§ 1.980 Administrative detention of drugs.

(a) *General.* This section sets forth the procedures for detention of drugs believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of drugs encountered during inspections that may be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. Drugs that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA

terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) *Criteria for ordering detention.* Administrative detention of drugs may be ordered in accordance with this section when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act, has reason to believe that a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, is adulterated or misbranded.

(c) *Detention period.* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA District Director in whose district the drugs are located determines that a greater period is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action, in which case the District Director may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(d) *Issuance of detention order.* (1) The detention order must be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the drugs are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the drugs are located. If the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are detained, a copy of the detention order must be provided to the owner or user of the drugs if the owner's or user's identity can be readily determined.

(2) If detention of drugs in a vehicle or other carrier is ordered, a copy of the detention order must be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order must include the following information:

(i) A statement that the drugs identified in the order are detained for the period shown;

(ii) A brief, general statement of the reasons for the detention;

(iii) The location of the drugs;

(iv) A statement that these drugs are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative;

(v) Identification of the detained drugs;

(vi) The detention order number;

(vii) The date and hour of the detention order;

(viii) The period of the detention;

(ix) The text of section 304(g) of the Federal Food, Drug, and Cosmetic Act and paragraphs (g)(1) and (g)(2) of this section;

(x) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and

(xi) The location and telephone number of the FDA district office and the name of the FDA District Director.

(e) *Approval of detention order.* A detention order, before issuance, must be approved by the FDA District Director in whose district the drugs are located. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum within FDA as soon as possible.

(f) *Labeling or marking a detained drug.* An FDA representative issuing a detention order under paragraph (d) of this section must label or mark the drugs with official FDA tags that include the following information:

(1) A statement that the drugs are detained by the U.S. Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the drugs must not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) *Appeal of a detention order.* (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA District Director in whose district the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized.

(3) Any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that:

(i) The detention order under paragraph (d) of this section, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter;

(ii) A request for a hearing under this section should be addressed to the FDA District Director;

(iii) The last sentence of § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section;

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., regional food and drug directors, who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also must decide the appeal, must be a regional food and drug director (i.e., a director of an FDA regional office listed in part 5, subpart M of this chapter) who is permitted by § 16.42(a) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer must, within 5 working days, hold the hearing and render a decision affirming or revoking the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than

within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer must hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer must decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the detention order but does not request a regulatory hearing, the presiding officer must render a decision on the appeal, affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the drugs continue to be detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(9) If the presiding officer revokes a detention order, FDA must terminate the detention under paragraph (j) of this section.

(h) *Movement of detained drugs.* (1) Except as provided in this paragraph, no person may move detained drugs within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the drugs are moved for this purpose, the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible district office official, of the movement of the drugs. As soon as the drugs are put in final form, they must be segregated from other drugs, and the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible district office official, of their new location. The drugs put in final form must not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible district office official, may approve, in writing, the movement of detained drugs for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the drugs;

(ii) To destroy the drugs;

(iii) To bring the drugs into compliance;

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible district office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained drugs under paragraph (h)(3) of this section, the detained drugs must remain segregated from other drugs and the person responsible for their movement must immediately orally notify the official who approved the movement of the drugs, or another responsible FDA district office official, of the new location of the detained drugs.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of drugs under this paragraph, the required tags must accompany the drugs during and after movement and must remain with the drugs until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) *Actions involving adulterated or misbranded drugs.* If FDA determines that the detained drugs, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the drugs or the responsible individuals, or both, or request that the drugs be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act under FDA's supervision.

(j) *Detention termination.* If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the drugs to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) *Recordkeeping requirements.* (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained drugs are manufactured, processed, packed, or held, must have, or establish, and maintain adequate records relating to how the detained drugs may have become adulterated or misbranded, records on any distribution of the drugs before and after the detention period, records on the correlation of any in-process detained drugs that are put in final form under paragraph (h) of this section to the completed drugs, records of any changes in, or processing of, the drugs permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph must be provided to FDA on request for review and copying. Any FDA request for access to records required under this paragraph must be made at a reasonable time, must state the reason or purpose for the request, and must identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph must be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the Agency determines that the drugs are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter (e.g., the good manufacturing practice regulation in part 211 of this chapter).

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 4. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467F, 679, 821, 1034; 42 U.S.C. 201–262, 263b, 364.

■ 5. Revise the first sentence of § 16.1 paragraph (b)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) Statutory provisions: Section 304(g) of the act relating to the administrative detention of devices and drugs (see §§ 800.55(g) and 1.980(g) of this chapter).

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Dated: May 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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